CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Food and Drug Administration
Documents Management Branch
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Rockville, MD 20852
Docket No. 98N-0359

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate this opportunity to comment on the Food and Drug Administration's (FDA's) program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000. CSPI is a non-profit consumer advocacy organization focusing largely on nutrition and food-safety policies. We accept no industry or government funding and are supported almost entirely by the one million subscribers to our *Nutrition Action Healthletter*.

Question 1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

There are numerous issues that are not being adequately addressed in the current plan:

1. Egg safety. Despite CSPI's petition in 1997 to FDA requesting that FDA implement on-farm controls for *Salmonella enteritidis* in shell eggs, FDA's recent proposals on egg safety have not addressed this critical area. The egg industry, at recent public meetings, indicated its support for on-farm controls. FDA's continued failure to mandate these controls is a disservice to the American public, as well as to the egg industry itself. In addition, the goal of 50% reduction in SE illnesses by 2005 is inadequate to address the decade-long inattention to the problem of SE in eggs.

Recommendation: FDA should seek to eliminate shell eggs as a source of SE food-borne illness by 2005 by mandating on-farm controls, that are monitored using microbial testing, coupled with diversion of all eggs from SE-positive flocks.

2. Seafood safety. Implementation of the 1997 seafood HACCP regulation has been a failure. The goal of 50% compliance in the second year of implementation is inadequate. It is especially disappointing to see FDA settle for such low compliance two years after it hired 80 new inspectors to oversee HACCP implementation in the seafood industry. In addition, FDA's regulation should include microbial testing to assure that the seafood industry is held to

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performance standards for pathogen reduction.
Recommendation: FDA should seek full compliance with the HACCP regulation in the year 2000. Plants which are not in compliance should be closed down. The HACCP regulation should be amended to include mandatory microbial testing.

3. Shellfish safety. Vibrio vulnificus, parahaemolyticus, and *cholera* non-01, pathogens common to raw molluscan shellfish, are all known to cause severe human illnesses and even death. FDA's actions to date in addressing these hazards have proven ineffective. Over 100 consumers have died since 1989 from just one of these hazards, *Vibrio vulnificus.* If FDA intends to fulfill its public health mandate, the agency must take immediate action to protect consumers from these potentially deadly pathogens.
Recommendation: FDA should implement a public-health-based performance standard for pathogenic strains of *Vibrio* in shellfish intended for raw consumption.

4. Fruit and vegetable safety. FDA's response to numerous recent fruit and vegetable outbreaks has been to develop voluntary guidelines for fruit and vegetable growers and processors. These Good Agriculture Practices (GAPs) and Good Manufacturing Practices (GMPs) are too vague and generic to provide any meaningful information to the industry. They should be made more crop-specific to account for the important differences in preventive measures that are applicable to diverse fruit and vegetable crops. In addition, while the guidance document identifies water and manure as important sources of contamination, it falls short of prescribing specific measures to ensure that these farm inputs are used safely.
Recommendation: FDA should set tough mandatory standards for growing fruit and vegetables for human consumption and should enforce them with an on-farm inspection program. In addition, FDA should send inspectors to foreign countries to ensure that their safety systems for fruit and vegetable growers provide an appropriate level of public health protection. FDA should prohibit the importation of fresh produce from those countries where this is not the case.

5. Food safety inspections. In addition to inadequate emphasis on certain products, critical pieces of FDA's food safety mission are not under CFSAN's purview. For example, there is no direct control over FDA's inspection resources. Therefore, CFSAN's inspection priorities may be subsumed by other priorities in the agency.
Recommendation: CFSAN should have direct control over a dedicated food-safety inspection force.

Question 2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

- **President's Food Safety Initiative**

Food-safety issues merit top priority at the agency. Our research on foodborne-illness outbreaks indicates that the highest risk products under FDA's jurisdiction are shell eggs; fruits and vegetables, including juice products; and seafood, including shellfish. These products should command the highest priority among FDA's food-safety activities. Increasing domestic and import inspections is also critical to revitalizing FDA's program.

- **Enhancing the Scientific Base for HACCP**

The scientific basis of the HACCP programs should be improved by requiring mandatory microbial sampling and by setting performance standards for foods that are covered by HACCP systems. HACCP systems work best when industry plans are subjected to continual verification using microbial testing to check for compliance with strong performance standards. FDA should restructure all of its HACCP programs to assure that they are pathogen reduction programs.

- **Food Additive Regulation**

We urge the agency to continue its support of the Delaney Clause for food and color additives. Statements by former Commissioner David Kessler confirm the need to maintain the Delaney Clause. CFSAN should continue to support the Delaney Clause as an "insurance policy" against approval of cancer-causing food additives.

FDA's treatment of food additive approvals is an area of great concern for CSPI. It seems that sometimes the agency has turned the legal standard for approving food additives on its head. Instead of requiring a company to prove the safety of a proposed food additive, the agency seems to have shifted the burden to the public-health community to prove harm. Recent examples include the approval of olestra and acesulfame-K.

The Food Advisory Committee has evinced serious credibility problems. The committee has had too much industry representation, in the form of both industry employees and industry consultants in the academic community. A more well-balanced committee is needed if FDA hopes to restore credibility to the Food Advisory Committee and its recommendations regarding food additive approvals.

The FDA should act promptly on petitions to restrict the use of, or to require better labeling of, potassium bromate, carmine, sorbitol, and salatrim.

• Food Labeling

The FDA should promptly propose regulations to update the nutrition label. The agency should specifically require that *trans* fatty acids be counted as saturated fat and require the listing of both total and added sugars content, along with the percentage of a newly designated Daily Value for added sugars. The agency should also require better labeling of food additives like caffeine and MSG that can cause health problems.

Enforcement of the FDA's food-labeling requirements has waned in recent years. As a result, misleading claims on food labels are increasing. To remedy this problem, we urge the following steps:

- Promptly appoint a permanent director of the Division of Food Labeling.

- Promptly propose regulations pursuant to the U.S. Court of Appeals decision in *Pearson v. Shalala* that require all health claims not supported by significant scientific agreement to state immediately before such claim, and in lettering as large and conspicuous as the claim, the following statement: "The Food and Administration does not consider the following statement to be scientifically valid:"

- Immediately propose implementing regulations for the health and nutrition claims sections of the FDA Modernization Act of 1997. Those regulations should require public docketing of all health claim notifications and confirm that all health claims must be supported by significant scientific agreement. In addition, such regulations should specify that health and nutrition claims based on authoritative statements of other government agencies are limited to statements that were intended to constitute dietary recommendations.

- Cease approval of product-specific health claims for breakfast cereals and other foods. Such claims provide consumers with potentially misleading dietary advice that is not supported by the public-health community.

- Resume strict enforcement of the law with particular attention to violations of section 403(a) of the Act, including misleading claims pertaining to ingredients such as whole wheat, fruits, and vegetables. Violations of the Act that cannot be handled by the FDA due to resource constraints should be systematically delegated to state enforcement officials.

- Close the food standards review initiative. The initiative is opposed by consumer organizations and some segments of the food industry. In an era of increasingly limited resources, such efforts should be terminated.

- **Functional Foods**

The FDA should continue enforcing the food additive provisions of the law and prevent companies from adding dietary supplements and other ingredients to foods that are not Generally Recognized as Safe. Foods must not be allowed to masquerade as dietary supplements, in order to avoid sections of the law pertaining to food additives.

The FDA should also issue regulations governing structure/function claims for foods. The agency should require that such claims be based on universally accepted statements of fact regarding the effect of a nutrient on the structure or function of the body. In addition, the FDA should apply to structure/function claims the nutrient qualification and disqualification levels that apply.

- **Dietary Supplement Regulation**

The FDA is burdened with a weak law that limits the agency's authority to protect the public from unsafe and misleadingly labeled supplements. The agency should build a record detailing the need for greater authority, and issue a report on problems caused by the current law. In addition, the agency should adopt a containment strategy which helps ensure that problems with the regulation of dietary supplements do not spread to the regulation of health claims for foods and safety and efficacy requirements for drugs. The FDA also should tighten its definition of "disease" in order to prohibit structure/function claims that are tantamount to implied disease prevention claims and take prompt enforcement actions against companies that make misleading claims.

- **International Affairs**

The FDA should join with the Environmental Protection Agency and take the lead to see that the Administration's trade polices are not only consistent with the F D&C Act, but also that they further the objectives of the Act. The FDA should ensure that public health takes precedence over trade concerns and should help set a world-class standard that will be followed by countries that import foods to the U.S. by urging that international standards be harmonized upward. The agency should also promptly respond to the recommendations of the Trans-Atlantic Consumer Dialogue.

Question 3. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions can be made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

1. Rapid detection methods for bacteria in foods.

2. Pilot studies on effective inspection techniques for different types of food establishments, with initial emphasis on the riskiest foods.

3. Research aimed at developing effective on-farm controls for eggs and produce.

Question 4. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities? Please identify specific activities in your answers.

International compliance with the seafood HACCP regulation should be a top priority. With 50% of the seafood consumed in the U.S. coming from foreign sources, consumers face a higher risk of seafood-borne illnesses if imported seafood doesn't meet our minimal standards. In addition, FDA's lax approach to domestic HACCP implementation raises concerns that FDA is not adequately enforcing HACCP with our international trading partners.

FDA should also put a high priority on conducting audits of foreign counties that import food to the U.S. Such on-site audits are conducted by USDA's Food Safety and Inspection Service for all countries that import meat or poultry products to the U.S. to ensure that the countries' programs are equivalent to the U.S. program. Where countries are not found to be equivalent, imports should be disallowed until the country is in compliance with our standards.

Sincerely,

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